Plasma Standards and The American Association of Blood Banks (AABB)

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American Association of Blood Banks

- Professional society for over 8000 individual and 1800 institutional members involved in blood banking, transfusion medicine and cellular therapies.
- Members are responsible for virtually all volunteer blood collected and more than 80% of blood transfused in the US.

American Association of Blood Banks

- Founded in 1947, AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.
- The cornerstone of this priority continues to be the Association's standard-setting and accreditation activities.

Standards of the AABB

- The AABB published its first edition of *Standards for Blood Banks and Transfusion Services (BB/TS Standards)* in 1958 and began its accreditation program in the same year.
- The *BB/TS Standards* Program Unit is comprised of volunteer professionals who are leaders in the fields of blood banking and transfusion medicine.

Standards of the AABB

- *Standards* are scientifically-based, clinical practices that include cGMPs and quality assurance principles.
- *Standards* are updated based on changing practices and technologies.

Standards of the AABB

- Broad input is sought and includes AABB members, external agencies, and the public.
- External representatives to BB/TS Program Unit include ARC, ACOG, DoD, CAP, FDA, and CA.

What Is A Standard?

- Imperitive statements that include quality and operational requirements.
- Required goals, not methods.
- Standards are scientifically-based, clinically sound, unambiguous requirements that provide the basis for the AABB's accreditation program.
- Minimum requirements that may be exceeded in practice.

Quality Systems Essentials

- Organization
- Resources
- Equipment
- Supplier and Customer Issues
- Process Control
- Documents and Records
- Deviations and Non-conformances
- Assessments
- Process Improvement
- Facilities and Safety

Standards of the AABB

- *Standards* specifically addressing recovered plasma have been included since the 21st edition of *BB/TS Standards.*
- Based on the outcomes of this workshop, the proposed rule *Revision to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma* and other scientifically-based, clinically sound practices, additional requirements for recovered plasma can be generated.

Standards of the AABB

- Tomorrow, I will review the AABB Task Force on Recovered Plasma proposed requirements for a new product, Plasma for Manufacture.

Comparison of Selected Plasma Requirements

Analysis of US vs. EU Freezing and Storage Requirements for Plasma for Fractionation, FFP and Cryoprecipitate

Plasma for Fractionation EU Requirements

Freezing time and temperature for Plasma for Fractionation are governed by the European Pharmacopoeia 4.5 Monograph titled Human Plasma for Fractionation (0853 - corrected).

Collection method	Final Product	Freezing requirements	Time from collection to freeze	Separation from Cellular Elements	Storage (includes transport)
Apheresis	For recovery of proteins that are **labile**	Frozen by cooling rapidly at minus 30 C or below	As soon as possible and at the latest w/in 24 hours of collection	N/A	At or below minus 20 C
Apheresis	**not labile**	Not addressed			
Whole Blood	For recovery of proteins that are **labile**	Separated and frozen by cooling rapidly at minus 30 C or below as soon as possible at the latest w/in 24 hours of collection			At or below minus 20 C
Whole Blood	For recovery of proteins **not labile**	Separated and frozen at minus 20 C or below as soon as possible and at the latest w/in 72 hours of collection			At or below minus 20 C

Analysis of US vs. EU Freezing and Storage Requirements for Plasma for Fractionation, FFP and Cryoprecipitate

Plasma for Transfusable Components - <u>US Regulations</u> (AABB Standards 22nd ed.

	Collection Method	**Freeze time**	**Freeze Temp**	**Storage**
FFP	Whole blood and apheresis (separation not specified)	8 hours CPD, CP2D, CPDA-1 or w/in 6 hrs in ACD or as FDA cleared.	Less than or equal to minus 18 C	Minus 18 or below for one year Minus 65 C or below 7 years (with FDA approval)
FFP 24 hours	Whole blood and apheresis	W/in 24 hours of collection	Less than or equal to minus 18 C	
Cryo	N/A			Minus 18 or below for one year